

Application 09/924,233
Page 28

REMARKS

Examiner refers to an Information Disclosure Statement from October 2001. Applicant has no record of sending such an IDS. There were a large number of references in the original application which should be part of the listing of references when this application eventually issues. If Examiner needs a list, please advise the applicant's attorney.

Claim Rejections under 35 USC §112

Examiner has rejected claims 3,18, 19, 21 -25, 34- 37 ad 42 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended as Examiner suggested. Examiner is thanked for the careful review of these claims.

Claim Rejections under 35 USC §102

Examiner has rejected claims 1 and 38 under 35 USC §102(e) as being anticipated by Lemelson (US 5,993,378).

It is the Examiner's position that Lemelson (US 5,993,378), which in turn refers to its earlier patent (US 4,900303), anticipates, or contains all of the elements of the instant invention as claimed.

For prior art to anticipate under §102, every element of the claimed invention must be identically disclosed, either expressly or under principles of inherency, in a single reference. Coming Glass Works v. Sumitomo Electric, 9 U.S.P.Q. 2d 1962, 1965 (Fed. Cir. 1989).

Even if incorporation by reference of one patent into another is proper to qualify the selected

Application 09/924,233

Page 29

material as a single reference, and Applicant traverses this idea, it is Applicant's position that both Lemelson references are directed to catheters or tubular instruments for passage through body channels. While these catheters described can be adapted for implanting materials or dispensing materials at remote locations within a body, they aren't injection devices as described in the present invention as a replacement for a syringe that dispenses medicaments immediately under the skin of the subject animal. Neither of the Lemelson references are directed to the problem Applicant addresses, namely, quick and accurate injection of a liquid medicament through the skin of the subject, especially in a group of subjects. Catheters are used within a body cavity, not at the surface. The fact you can stick a needle on the end of a catheter does not teach or suggest a solution to the problem with which the claimed invention is concerned. Neither of the Lemelson references are in the same field of endeavor nor pertinent to the problem to be solved.

Additionally, it is respectfully submitted that with newly amended claims 1 and 38, these rejections have been obviated. It is respectfully submitted that amended claims 1 and 38 are neither anticipated by nor obvious over Lemelson '378. The withdrawal of this rejection is seen to be in order and is requested.

Claim Rejections under 35 USC §103

Examiner has rejected claims 2 and 40 under 35 USC §103(a) as being unpatentable over Lemelson '378 and Nichoff (US 5,928,197).

Examiner has taken the position that Lemelson teaches all the claimed subject matter except for the emergency stop and that Nichoff provides the stop.

As stated above and repeated here, Lemelson doesn't have all of the elements of the claimed subject matter less the emergency stop. Additionally, in manual mode, the emergency stop of Nichoff requires the user to simultaneously push a motion button 46 or 47 and an enable button 48. Once motion is initiated, the operator may release one of the buttons and the motion will be

Application 09/924,233
Page 30

maintained at a constant velocity in the same direction so long as any of the buttons is held down (col. 5, lines 1 - 11 *Inter alia*). In the device of Applicant, pushing trigger makes the injection device "go" and pushing the emergency stop causes the injection to stop immediately. This differentiates the use and action of the emergency stop of Applicant.

It is impermissible within the framework of a § 103 to pick and choose from a reference only so much of it as will support a conclusion of obviousness to the exclusion of other parts necessary to a full appreciation of what the reference fairly suggests to one skilled in the art. Bausch & Lomb, 230 USPQ at 419.

The remarks made above in regard to the rejections under 35 USC §102 over Lemelson are equally pertinent to the present rejection and are thus repeated here. Additionally, with the amendment of the base claims, 1 and 38, this rejection is obviated with respect to claims 2 and 40.

It is respectfully submitted that amended claims 2 and 40 are neither anticipated by nor obvious over Lemelson '378 in view of Niehoff. The withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claims 3 and 41 under 35 USC §103(a) as being unpatentable over Lemelson '378 in view of Denance (US 5,034,003).

Examiner has taken the position that Lemelson teaches all the claimed subject matter except for the safety interlock and that Denance provides such.

The remarks made above and the cases cited in regard to the rejections over Lemelson are equally pertinent to the present rejection and are thus repeated here.

With the amendment of the base claims, 1 and 38, this rejection is obviated with respect to these claims.

Further, in the invention of Applicant, page 2, line 19 (*inter alia*), the safety interlock is provided that prevents injection until a retractable resilient member 152 is forced to a second, retracted position, to complete an electrical circuit permitting injection to take place. Both the electrically connected trigger and interlock must be depressed fully for injection to occur. In

Application 09/924,233
Page 31

Denance '003, an element acting as a safety valve is disposed at the level of the injection needle (col. 5, line 58, *inter alia*), the device acting to prevent the problem of leakage of the injection fluid. The lever 39 is a detector of penetration of the needle into the skin (col. 6, lines 17, and following). The lever 39 acts directly on the wall of the mounting for the safety valve 36. The lever 39 thus acts directly on the safety valve 35. The safety valve 35 is disengaged from the opening 41 which permits circulation of the liquid between the syringe and the needle. These are mechanical means. As soon as penetration of anything occurs, the valve is opened. In the invention of Applicant, an accidental penetration of skin doesn't result in an injection. The user must simultaneously push the trigger. The safety interlock of Applicant serves to delay injection until the needle is **completely** inserted, thus acting to prevent this very serious accident. The careless operator can still stab himself, but the pain of the stab causes the operator to immediately withdraw the injection device avoiding self injection. Denance employs a safety valve 35 to block the flow of injectable from the syringe until the needle is inserted. This appears to relate to the construction of the syringe in that the injectable would otherwise freely flow from the syringe without a valve to prevent it. It appears that safety of the operator is not the point of concern in Denance.

It is impermissible within the framework of §103 to pick and choose from a reference only so much of it as will support a conclusion of obviousness to the exclusion of other parts necessary to a full appreciation of what the reference fairly suggests to one skilled in the art Bausch & Lomb, 230 USPQ at 419.

Even if the base claim were not now in allowable form, Denance adds nothing to the combination of Lemelson that would make these claims obvious. It is respectfully submitted that any teachings of Denance with regard to safety interlock devices can garner the Examiner nothing in attempting to bolster the rejection of claims 3 and 41 since the rejection of the base claims, as amended, is not on solid ground. The withdrawal of this rejection is seen to be in order and is requested.

Application 09/924,233
Page 32

Examiner has rejected claims 4, 5, 9 and 42 under 35 USC §103(a) as being unpatentable over Lemelson '378 in view of Kobayashi (US 4,469,481).

Examiner has taken the position that Lemelson teaches all the claimed subject matter except for the dose limiter controlled by a photo-optic sensor.

The remarks made above in regard to the rejections under 35 USC §102 over Lemelson are equally pertinent to the present rejection and are thus repeated here. With the amendment of the base claims, 1 and 38, putting them in allowable form, this rejection is obviated with respect to these claims. The withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claims 6, 10, and 13-15 under 35 USC §103(a) as being unpatentable over Lemelson '378 and Kobayashi '481 as applied to claims 5 and 9 and further in view of Denance '003.

Examiner has taken the position that Lemelson as modified by Kobayashi teaches all of the claimed subject matter except for an indicator light.

With regard to claim 13, the safety interlock of Denance was distinguished above and arguments and cases are repeated here.

With the amendment of the base claims, 1 and 13 putting them in allowable form, this rejection is obviated with respect to these claims. The withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claims 7, 11, and 16 under 35 USC §103(a) as being unpatentable over Lemelson '378, Kobayashi, '481, and Denance '003 as applied to claims 6 and 10 above, and further

Application 09/924,233
Page 33

in view of Kriesel et al (US 5,840,071).

Examiner has taken the position that Lemelson as modified by Kobayashi and Denance teaches all the claimed subject matter except for the indicator for when the injection fluid is low and that Kriesel supplies that element.

In the device of Applicant, indicator lights are located on all hand-held injection devices 40, 40', 40", 40''' & 40'''. Low serum bottle level is indicated by red LCD signal light 50 set to the count and will light when the bottle is down to approximately 10% of capacity, e.g. in a 250ml bottle, signal light 50 lights when the bottle is down to about 25, as set by means of the control unit.

The device of Kriesel uses colored films to be displayed signifying differences of fluid pressure within the system (col. 11, lines 35-40, *inter alia*). This is mechanical means as opposed to electrical means based on the 'count' of the amount of fluid administered. The device of Applicant represents an advancement in the art of indicators.

There is no teaching in Kriesel or in other references that would lead one of ordinary skill in the art to combine the relevant teachings of the references. In re Fine, 5, USPQ 2d 1596, 1598 (Fed. Cir 1988).

The remarks made above in regard to the rejections under 35 USC §102 over Lemelson, and the cases cited regarding § 103 are equally pertinent to the present rejection and are thus repeated here.

It is respectfully submitted that Kriesel adds nothing to the combination of Lemelson, Kobayashi and Denance. With the amendment of the base claims, 1 and 9, 13 putting them in allowable form, this rejection is obviated with respect to these claims. The withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claim 19 under 35 USC §103(a) as being unpatentable over Lemelson '378 in view of Wallach (US 3,949,746).

Application 09/924,233
Page 34

Examiner takes the position that Lemelson teaches all the claimed subject matter except for a marking tip and that Wallach supplies a marking tip.

With the amendment of the base claims, 1 and 19 putting them in allowable form, this rejection is obviated with respect to these claims. The withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claims 22 and 23 under 35 USC §103(a) as being unpatentable over Lemelson '378 and Wallach '746 as applied to claim 19 and further in view of Exodax 20/50 owners manual (1993).

Examiner takes the position that Lemelson as modified by Wallach teaches all the claimed subject matter except for quick connect fittings shown in the Exodax manual.

With the amendment of the base claim 1 putting it in allowable form, this rejection is obviated with respect to claims 22 and 23. No other hand-held injection device referenced has the capability to select from a series of injectors and install the desired injector to a control unit for use in a particular circumstance, ex. injection of cow ears. There is no teaching in Exodax or the other references that would lead one of ordinary skill in the art to combine the relevant teachings of the references. In re Fine, 5, USPQ 2d 1596, 1598 (Fed. Cir 1988).

Withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claims 24 and 25 under 35 USC §103(a) as being unpatentable over Lemelson '378, Wallach, '746, and Exodax as applied to claim 23 above, and further in view of Kobayashi '481.

Examiner has taken the position that Lemelson as modified by Wallach and Exodax teaches all the claimed subject matter except for controlling the dose with the use of a photo-optic sensor.

Application 09/924,233
Page 35

The discussion above regarding the photo-optic sensor of Kobayashi is repeated here. It is respectfully submitted that Kobayashi adds nothing to the combination of Lemelson, Wallach and Exodax. The remarks made and cases cited above in regard to the rejections over Lemelson are equally pertinent to the present rejection and are thus repeated here.

With the amendment of the base claim, 1 putting it in allowable form, this rejection is obviated with respect to claims 24 & 25. The withdrawal of this rejection is seen to be in order and is requested.

Examiner has rejected claims 26 and 30 under 35 USC §103(a) as being unpatentable over Lemelson '378 in view of Reimels (US 5,580,347).

Cancellation of these claims renders this objection moot.

New Claims

Claim 44 was added to claim with more specificity the headlamp and is supported at page 16, line 13, *inter alia*.

Claim 54 is supported at page 17, line 19 *inter alia*.

New claims 45 -70 are presented to bring the claims into alignment with claims allowed in foreign jurisdictions. No new matter is involved.

The rest of the references cited by Examiner have been considered and the newly presented claims are considered to recite an invention patentable thereover

Allowable subject matter

Examiner has indicated that claim 39, while objected to as being dependant on a rejected base claim, but would be allowable if rewritten in independent form.

Application 09/924,233

Page 36

Claims 38 and 39 have been amended to conform to Examiner's suggestion and now are viewed to be in allowable form and such is requested.

Examiner has indicated that claims 34 - 37 would be allowable if rewritten or amended to overcome the rejections under 35 USC §112, 2nd paragraph.

Claim 34 has been amended to conform to Examiner's suggestion and claims 34-37 are now viewed to be in allowable form and such is requested.

Examiner has indicated that claims 18 and 21 would be allowable if rewritten to overcome the rejections under 35 USC §112, 2nd paragraph.

Claims 18 - 21 have been amended to conform with Examiners suggestions and now are viewed to be in allowable form and such is requested

Claims 34- 37 have been previously determined to be in allowable form and such is requested.

CONCLUSION

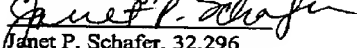
It is respectfully submitted that, with the above remarks and amendments to the claims, each and every one of Examiner's objections and rejections to the present claims has been overcome. The prompt issuance of a Notice of Allowance is seen to be in order and is solicited to be forthcoming. Should the Examiner consider that any minor matters remain to be resolved prior to the issuance of a Notice of Allowance, the Examiner is requested to telephone the undersigned attorney of record to achieve prompt resolution thereof.

Application 09/924,233
Page 37

Respectfully submitted,

Wilbur L. Eidson,

By his attorney,



Janet P. Schafer, 32,296

SCHAFFER LAW OFFICE, P.A.

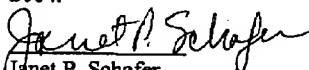
727 Torchwood Circle

New Brighton, MN 55112

(651)-633-8261

CERTIFICATE OF FACSIMILE TRANSMISSION

I certify that this Amendment, Amendment Transmittal Letter, Certificate of Facsimile Transmission, and any other papers mentioned as included herein, is being transmitted by facsimile to the Examiner at Group 3763 at fax number (703)872-9302 at 5 PM central daylight time, February 27, 2004.



Janet P. Schafer
Patent Attorney